



Food and Drug Administration
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September 24, 2015

CyMedica Orthopedics, Inc
c/o David Yungvirt
Third Party Review Group, LLC
45 Rockefeller Plaza, Suite 2000
New York, NY 10111

Re: K150413

Trade/Device Name: QB1 Powered Muscle Stimulator System (NMES) & Transcutaneous
Electrical Nerve Stimulator System (TENS); QB-1000

Regulation Number: 21 CFR 890.5850

Regulation Name: Powered Muscle Stimulator

Regulatory Class: Class II

Product Code: IPF, GZJ

Dated: March 3, 2015

Received: March 4, 2015

Dear Mr. Yungvirt:

This letter corrects our substantially equivalent letter of September 15, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health Enclosure

Enclosure

Indications for Use

510(k) Number (if known)

K150413

Device Name

QB1 Powered Muscle Stimulator System (NMES) & Transcutaneous Electrical Nerve Stimulator System (TENS)

Indications for Use (Describe)

The QB1 Powered Muscle Stimulator System (NMES) & Transcutaneous Electrical Nerve Stimulator System (TENS); QB-1000 is a multifunctional electrotherapy device with two treatment modes that allow for neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS).

Indications for Use:

As an NMES device, indications are for the following conditions:

- Relaxation of muscle spasms
- Retardation or prevention of disuse atrophy
- Increasing local blood circulation
- Re-educating muscles
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

As a TENS device, indications are for the following conditions:

- Symptomatic relief and management of chronic intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

CyMedica Orthopedics, Inc. QB1 NMES and TENS Systems

1- SUBMITTER

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510(k) Summary Preparation Date February 13th, 2015

510(k) Number K150413

2- DEVICE

Trade/Proprietary Name: QB1 Powered Muscle Stimulator System (NMES) &
Transcutaneous Electrical Nerve Stimulator System
(TENS); QB-1000

Common Name: Muscle stimulator

Classification Names: Powered muscle stimulator (21 CFR 890.5850)

Product Code: NMES device: IPF
TENS device: GZJ

Device Class: 2

These devices are reviewed by the Division of Neurological and Physical Medicine Devices.

3- PREDICATE DEVICE

Name & 510(k) Number: Kneehab XP, K110350
MediStim XP (AvivaStim XP), K082011

Manufacturer: Bio-Medical Research, Ltd.

4- DEVICE DESCRIPTION

The CyMedica Orthopedics QB1 System is a multifunctional electrotherapy device with two stimulation channels and two treatment modes that allows for neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS). The principles of electrotherapy emulate the process observed during a voluntary muscle contraction. The QB1 system delivers stimulation based on the principles of NMES and TENS. NMES pulses stimulate motor points of target muscles, causing a muscle contraction. This can help re-educate and strengthen muscles following an injury or surgery. TENS blocks the pain signal sent from the affected area on nerve pathways.

The QB1 NMES and TENS systems are prescription devices in the USA and are intended to be used following the directions of a healthcare provider. The device may be used in a healthcare facility setting or by a patient or lay operator in a home environment.

In NMES mode, the QB1 system provides two therapeutic treatment programs: Post-Operative and Strength. Its simplified programming makes the device convenient for home use; after placing the electrodes and selecting the program as prescribed by a healthcare professional, the patient only needs to increase the intensity to a comfortable level to begin therapy. The QB1 NMES Post-Operative and Strength programs utilize an electrical stimulus that, when properly applied, activates specific muscles or muscle groups to help treat disuse muscle atrophy and to reeducate muscles. This is achieved via a closed loop feedback system that minimizes energy delivery to the targeted treatment areas.

In NMES mode, the QB1 system consists of a Conductive garment with an incorporated NMES pod, User Interface device with a battery charger, NMES electrodes, and electrode gel.

The QB1 device also offers a TENS program for pain management. The QB1 TENS system consists of a TENS pod, User Interface device with a battery charger, TENS electrodes, and electrode gel.

The QB1 User Interface is programmed with an embedded software to manage the treatment programs and communicate with the User Interface touchscreen, NMES conductive garment, and TENS pod. The User Interface allows the user to select a treatment from the available treatment programs stored in the memory component of the NMES conductive garment and TENS pod. The User Interface utilizes a touchscreen and tactile buttons for user control. The User Interface device is powered by an internal rechargeable 3.7 V Lithium Ion battery that, when fully charged, can deliver at least three-20 minute treatments before requiring a recharge. The QB1

USB charger can fully recharge the battery in approximately five hours.

The QB1 system accessories include:

- QB1 electrodes for NMES application
- QB1 electrodes for TENS application
- QB1 electrode gel

5- INDICATIONS FOR USE

The QB1 System is a multifunctional electrotherapy device with two treatment modes that allow for neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS).

The intended use of QB1 NMES device, including any indications for use, is limited to use in rehabilitation, including providing adjunctive therapy in rehabilitation for medical purposes.

Indications for Use:

As an NMES device, indications are for the following conditions:

- 1) Relaxation of muscle spasms
- 2) Retardation or prevention of disuse atrophy
- 3) Increasing local blood circulation
- 4) Re-educating muscles
- 5) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- 6) Maintaining or increasing range of motion

Programs NMES Post-Op and NMES Strength provide the above indications.

Treatment Program	Pulse shape	Duration	Frequency	Pulse width	Duty cycle	Work cycle	Relaxation time	Contraction time	Rest time	Indications numbers
NMES Post-Op	Monophasic	20 min	50 pps	5 ms	25%	13 s	10 s	3 s	3.4 s	1, 2, 3, 4, 5, 6
								2 cycles		
NMES Strength	Monophasic	20 min	50 pps	5 ms	25%	12 s	10 s	1 s	1.4 s	1, 2, 3, 4, 5, 6
								5 cycles		

The QB1 TENS device is intended for pain relief.

As a TENS device, indications are for the following conditions:

- 7) Symptomatic relief and management of chronic intractable pain
- 8) Adjunctive treatment for post-surgical and post-trauma acute pain

Program TENS pain management provides the above indications.

Treatment Program	Pulse shape	Duration	Frequency	Pulse width	Duty cycle	Work cycle	Interphase interval time	Indications numbers
TENS Pain Management	Biphasic, symmetrical	20 min	100 pps	1 ms	20%	Continuous	4 ms	7, 8

6- COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

CyMedica Orthopedics, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the QB1 System is substantially equivalent in indications and design principles to predicate devices, which have been determined by FDA to be substantially equivalent to preamendment devices: Bio-Medical Research, Ltd, Kneehab XP device, K110350 and MediStim XP (AvivaStim XP), K082011. The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

The intended use, design, materials and functional characteristics of the QB1 System and the predicate devices are substantially the same. The subject device and predicate devices are for prescription use, portable, hand-held, and home healthcare environment devices. The power in QB1 device Kneehab XP device is derived from a rechargeable battery that is pre-installed in the unit. There are two channels of stimulation in all three devices. In all three devices the user needs to select the desired treatment program and adjust the intensity. All three devices employ a ramp-up, work, and rest phases.

The following table summarizes the technological characteristics of the subject device and predicate devices:

Parameter	QB1 NMES POST-OP	QB1 NMES STRENGTH	QB1 TENS	Kneehab XP-NMES	Kneehab XP-NMES	Kneehab XP-TENS	MediStim XP-NMES	MediStim XP-TENS
510(k) Number	K150413	K150413	K150413	K110350	K110350	K110350	K082011	K082011
Mode or Program Name	POST-OP	STRENGTH	TENS	Program 1	Program 5	Program 7	Program 1	Program 9
Waveform (e.g., pulsed monophasic, biphasic)	Pulsed Monophasic	Pulsed Monophasic	Symmetric Biphasic	Pulsed, Symmetrical, Biphasic	Pulsed, Symmetrical, Biphasic	Pulsed, Symmetrical, Biphasic	Pulsed, Symmetrical, Biphasic	Pulsed, Symmetrical, Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)	Complex	Complex	Complex	Square	Square	Square	Square	Square
Maximum Output Voltage (volts, rms) (+/- _____%)	3.4 @500Ω	3.4 @500Ω	0.18 @500Ω	25.5 @500Ω	25.8 @500Ω	40 @500Ω	33.5 @500Ω	20.9 @500Ω
	6.1 @ 2 k Ω	6.1 @ 2 k Ω	0.19 @ 2 k Ω	46.8 @ 2 kΩ	50.3 @ 2kΩ	61.7 @ 2kΩ	Error message for high load	Error message for high load
	8.5 @10 k Ω	8.5 @10 k Ω	0.20 @10 k Ω	34.0 @10 k Ω	34.2 @10k Ω	25.7 @10k Ω	Error message for high load	Error message for high load
Maximum Output Current (mA, rms) (+/- _____%)	6.8 @500Ω	6.8 @500Ω	0.36 @500Ω	51.0 @500Ω	51.6 @500Ω	80.0 @500Ω	67 @500Ω	41.8 @500Ω
	3.0 @ 2 k Ω	3.0 @ 2 k Ω	0.10 @ 2 k Ω	23.4 @ 2k Ω	25.2 @ 2k Ω	30.8 @ 2k Ω	Error message for high load	Error message for high load
	0.9 @10 k Ω	0.9 @10 k Ω	0.02 @10 k Ω	3.4 @10k Ω	3.4 @10k Ω	2.6 @10k Ω	Error message for high load	Error message for high load
Duration of primary (depolarizing) phase (μsec)	5000	5000	N/A (Continuous)	300	300	N/A (Continuous)	400	150
Pulse Duration (μsec)	5000	5000	1000	640	640	300	800	300
Frequency (Hz) [or Rate (pps)]	50	50	100	50	50	99	50	99
For interferential modes only: Beat Frequency (Hz)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	Yes	Yes	Yes	Yes	Yes	Yes
	Phase duration	N/A	1 ms	300 μs	300 μs	0.3 ms	400 μs	150 μs

Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)	126 @500Ω	126 @500Ω	0 @500Ω (Symmetric Biphasic)	0 @500Ω (Symmetric Biphasic)	0 @500Ω (Symmetric Biphasic)	0 @500Ω (Symmetric Biphasic)	0 @500Ω (Symmetric Biphasic)
Maximum Phase Charge, (μC)	126 @500Ω	126 @500Ω	43.0 @500Ω	25.2 μC @500Ω	23.4 μC @500Ω	19.8 μC @500Ω	0.14 μC @500Ω
Maximum Current Density (mA/cm², r.m.s.)	0.27 @500Ω	0.27 @500Ω	0.014 @500Ω	0.61 @500Ω	0.62 @500Ω	0.964 @500Ω	1.64 @500Ω
Maximum Average Current (average absolute value), mA	6.8 @500Ω	6.8 @500Ω	0.36 @500Ω	51.0 @500Ω	51.6 @500Ω	80.0 @500Ω	41.8@500Ω
Maximum Average Power Density, (W/cm²), (using smallest electrode conductive surface area)	0.001 @500Ω	0.001 @500Ω	2.6 E-6 @500Ω	0.016 @500Ω	0.016 @500Ω	0.039 @500Ω	0.034 @500Ω
Burst Mode	(a) Pulses per burst	150	50	250	250	N/A (Continuous Pulse)	
	(b) Bursts per second	0.087	0.23	0.10	0.10		
	(c) Burst duration (seconds)	3	1	5	5		
	(d) Duty Cycle: Line (b) x Line (c)	0.26	0.23	0.50	0.5		
ON Time (seconds)	312	276	Continuous	600	600	Continuous	Continuous
OFF Time (seconds)	888	924	Continuous	600	600	Continuous	Continuous
Additional Features (specify, if applicable)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

QB1 system differs from the Kneehab XP and MediStim XP devices in the following areas:

<u>Difference Area</u>	<u>Equivalence Discussion</u>
1 Output Regulation: QB1 system is a power regulated stimulator while Kneehab XP and MediStim XP are current regulated stimulators	Various voltage, current, and power regulated stimulators exist which indicate the control methodology used. The QB1 power controlled stimulator monitors both voltage and current. As shown in Section 18, the system has been fully tested per IEC 60601-1, 60601-1-2, 60601-1-6, 60601-1-11, 60601-2-10, IEC 62366 and meets all standard requirements and FDA guidance requirements. It adequately controls the stimulator outputs to the allowable ranges and within the tolerance limits provided in the standards and guidance, evidenced in IEC 60601-2-10. The QB1 output power levels are lower than Kneehab XP and MediStim XP as evidenced in Tables 2-4 of QB1 Design Verification & Validation, QB-0030-034, Section 018 of this submission. Accordingly, the QB1 power regulated stimulator poses no new safety risks and is substantially equivalent to the predicate.
2 Number of Electrodes: QB1 system uses three electrodes for NMES application while Kneehab XP uses 4 electrodes for NMES application.	Various electrical stimulation systems use two or more than two electrodes to deliver the stimulation energy. The choice of three electrodes versus the four electrodes is purely to target the thigh muscle regions desired. The main safety concern with number of electrodes is to have sufficient surface area and appropriate power output levels to prevent potential skin burns. As tested in QB1 Design Verification & Validation, QB-0030-034, Section 018 of this submission and evidenced in Tables 2-4, the maximum current densities of QB1 are lower than Kneehab XP. Accordingly, the difference in electrodes in the QB1 system poses no new safety risks and is substantially equivalent to the predicate.
3 Electrode Sizes: QB1 electrode sizes are 25.86, 51.61, and 51.61 cm ² while the Kneehab XP electrode sizes are 194, 74, 83, and 66 cm ² . Three MediStim XP electrode sizes are 20.25 cm ² , 25 cm ² , 49 cm ² .	Various electrical stimulation systems use different sizes of electrodes to deliver the stimulation energy. The choice of the QB1 electrodes is to have sufficient area for stimulation but to be sufficiently small to target the thigh muscle regions desired. The main safety concern with number of electrodes is to have sufficient surface area and appropriate power output levels to prevent potential skin burns. As tested in QB1 Design

Verification & Validation, QB-0030-034, Section 018 of this submission and evidenced in Tables 2-4, the maximum current densities of QB1 are lower than Kneehab XP and MediStim XP despite the smaller electrode sizes. Accordingly, the difference in electrode sizes in the QB1 system poses no new safety risks and is substantially equivalent to the predicate.

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| 4 Waveform and Shape:
QB1 NMES treatment waveform is a pulsed, monophasic and complex shape. QB1 TENS treatment waveforms is pulsed, symmetrical, biphasic, and complex shape. Kneehab XP and MediStim XP are pulsed, symmetrical, biphasic and rectangular shape with interphase interval. | Various electrical stimulation systems use various waveforms and shapes to deliver the stimulation energy. The design philosophy of the QB1 waveforms was to produce sufficient muscle contractions while maintaining comfort for the user. The QB1 waveforms are generally lower in amplitude and wider in pulse width to minimize the power required for muscle activation and maximize the comfort. The main safety concern with the waveform and shape is that the power output does not produce skin burns or other user health risks. As tested in QB1 Design Verification & Validation, QB-0030-034, Section 018 of this submission and evidenced in Tables 2-4, the QB1 waveforms are at lower voltage and current and therefore power levels than the Kneehab XP and MediStim XP. Accordingly, the difference in waveforms in the QB1 system poses no new safety risks and is substantially equivalent to the predicate. |
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Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

7- PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence.

To demonstrate the safety, the QB1 system was tested for electrical safety, electromagnetic compatibility, usability, biocompatibility, and risk management requirements.

To demonstrate the safety, the QB1 System was tested per the following standards:

- IEC 60601-1, Medical electrical equipment- General requirements for basic safety and essential performance
- IEC 60601-1-2, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility requirements

- IEC 60601-2-10, Medical electrical equipment- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulator
- IEC 60601-1-11, Medical electrical equipment- Part 1-11: General requirements for basic safety and essential performance- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-6, Medical electrical equipment- Part 1-6: General requirements for basic safety and essential performance- Collateral standard: Usability including IEC 62366: Application of usability engineering to medical devices
- IEC 62366: 2007, Medical devices -- Application of usability engineering to medical devices
- ISO 10993-1: 2009, Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5: 2009, Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2010, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization
- ISO 14971: 2007, Application of risk management to medical devices

In addition, to demonstrate the QB1 system effectiveness and performance substantial equivalency of the subject device, QB1 NMES and TENS system and the predicate devices Kneehab XP (K110350) and MediStim XP (K082011) were tested according to the following FDA guidance documents:

- FDA Final Guidance Document for Powered Muscle Stimulator 510(k), June 9, 1999
- FDA Draft Guidance Document, Class II special controls guidance document: Transcutaneous electrical nerve stimulator for pain relief, April 5, 2010

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the QB1 system, consisting of the User Interface, battery charger, conductive garment, and electrodes. The system complies with the IEC 60601-1, IEC 60601-2-10, and 60601-11 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification & Validation Testing

The device's software has been validated in accordance with the requirements set forth in the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical

Devices (May 11, 2005). The software validation tests demonstrated that the software version meets its design requirements.

Human Factors and Usability

The human factors and usability study was conducted to validate the usability of the QB1 system in the home environment. The results of the study support the instructions for successfully using the device as intended. The results of human factors and usability study substantiates the acceptability of the risks identified during the risk assessment activities. The QB1 system complies with the IEC 60601-1-6: 2010 for usability and IEC 62366: Application of usability engineering to medical devices.

8- CONCLUSION

Based on the performance testing and the supporting documentation, it can be concluded that the QB1 NMES and TENS system is safe, effective, and substantially equivalent to the predicate devices. The QB1 device output pulse parameters provide a safe and effective treatment for the NMES and TENS applications.

Based on the acceptable bench test results, QB1 compliance with the applicable standards, and low current and voltage values, the QB1 device is considered safe and as effective as the predicate devices, Kneehab XP (K110350) and MediStim XP (K082011) for its intended uses and indications for use. The QB1 NMES and TENS pulse parameters and waveform are selected and designed so they would provide a safe and effective treatment for the indications for use.